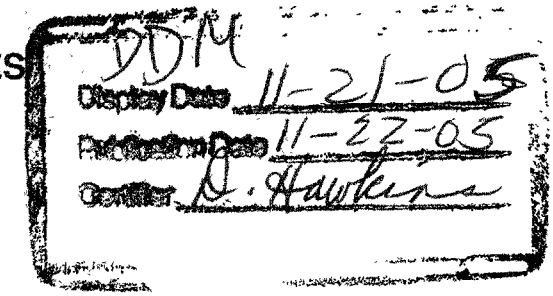
DEPARTMENT OF HEALTH AND HUMAN SERVICES



Food and Drug Administration

21 CFR Parts 1 and 11

[Docket No. 2005D–0356]

Guidance for Industry: Questions and Answers Regarding the Final Rule on Establishment and Maintenance of Records (Edition 2); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability of guidance.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "Questions and Answers Regarding Establishment and Maintenance of Records (Edition 2)." The guidance responds to various questions raised about section 306 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and the agency's implementing regulation, which requires the establishment and maintenance of records by persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. Such records are to allow for the identification of the immediate previous sources and the immediate subsequent recipients of food. Persons covered by the regulation must be in compliance by December 9, 2005, June 9, 2006, or December 11, 2006, depending on the size of the business.

DATES: Submit written or electronic comments on the agency guidance at any time.

ADDRESSES: You may submit comments, identified by Docket No. 2005D–0356, by any of the following methods:

NAD2

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name and Docket No(s). and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number(s), found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Denise Beavers, Office of Regulations and Policy (HFS–24), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1721.

SUPPLEMENTARY INFORMATION:

I. Background

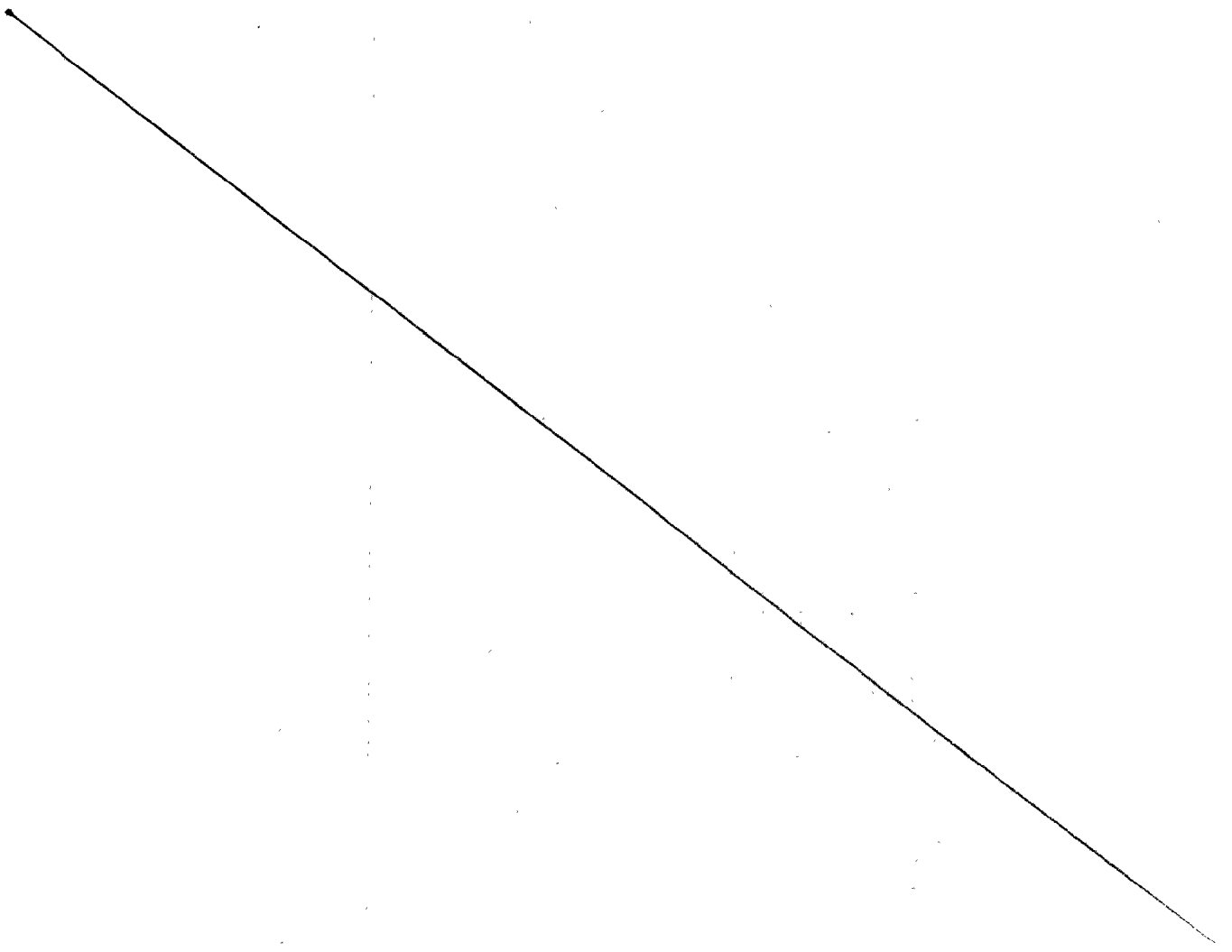
In the **Federal Register** of December 9, 2004 (69 FR 71562), FDA issued a final rule to implement section 306 of the Bioterrorism Act. The regulation requires the establishment and maintenance of records by persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. Such records are to allow for the identification of the immediate previous sources and the immediate subsequent recipients of food. Persons subject to the regulation are required to be in compliance by December 9, 2005, June 9, 2006, or December 11, 2006, depending on the size of the business. On September 12, 2005, FDA issued the first edition of a guidance entitled "Questions and Answers Regarding Establishment and Maintenance of Records." This guidance entitled "Questions and Answers Regarding Establishment and Maintenance of Records (Edition 2)" responds to questions about the final rule on records. It is intended to help the industry better understand and comply with the regulation in 21 CFR part 1, subpart J. FDA is issuing this guidance as a Level 1 guidance. The guidance represents the

agency's current thinking on the topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. Consistent with FDA's good guidance practices regulation § 10.115(g)(2) (21 CFR 10.115), the agency will accept comments, but it is implementing the guidance document immediately, in accordance with § 10.115(g)(2), because the agency has determined that prior public participation is not feasible or appropriate. As noted, the final rule requires that covered persons begin to establish and maintain records identifying the immediate previous sources and immediate subsequent recipients of food by December 9, 2005, June 9, 2006, or December 11, 2006, depending on the size of the business. Clarifying the provisions of the final rule will facilitate prompt compliance with these requirements and complete the rule's implementation.

FDA continues to receive large numbers of questions regarding the records final rule, and is responding to these questions under § 10.115 as promptly as possible, using a question-and-answer format. The agency believes that it is reasonable to maintain all responses to questions concerning establishment and maintenance of records in a single document that is periodically updated as the agency receives and responds to additional questions. The following four indicators will be employed to help users of this guidance identify revisions: (1) The guidance will be identified as a revision of a previously issued document, (2) the revision date of the guidance will appear on its cover, (3) the edition number of the guidance will be included in its title, and (4) questions and answers that have been added to the original guidance will be identified as such in the body of the guidance.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance at any time. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments and the guidance may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.



III. Electronic Access

Persons with access to the Internet may obtain the guidance at *http://www.cfsan.fda.gov/guidance.html.*

Dated: 11/15/05
November 15, 2005.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 05–????? Filed ??–??–05; 8:45 am]

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